

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No. : **10/538913**
Applicant : Venturelli
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Title : Endoluminal Prosthesis
TC/A.U. : 3731
Examiner : **McEvoy**
Docket No. : **5659**
Customer No. : 26936

Commissioner for Patents
Attn: Everett R. Williams, Patent Appeals Center
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPELLANTS' BRIEF ON APPEAL TO
THE BOARD OF PATENT APPEALS AND INTERFERENCES

This is appellant's brief on appeal to the Board of Patent Appeals and Interferences, from the final rejection of the application identified above.

REAL PARTY IN INTEREST

The real party in interest is Invatec, S.r.l., under an assignment recorded at reel 017387 frame 0193.

RELATED APPEALS AND INTERFERENCES

This is no related appeal or interference.

STATUS OF CLAIMS

Claims 1 - 49 and 51 - 56 are pending. Claims 50 and 57 have been canceled.
Claims 1 - 49 and 51 - 56 are on appeal.

STATUS OF AMENDMENTS

All amendments have been entered. The response after the final rejection did not contain any claim amendment.

SUMMARY OF THE CLAIMED SUBJECT MATTER

The invention described by claim 1 is an expandable endolumenal prosthesis (item 2, Fig. 1). In its non-expanded configuration, the prosthesis comprises:

- (a) a tubular body (Fig. 10) extending along a longitudinal axis (L, Fig. 1) and having a distal end (4) and a proximal end (5);
- (b) the tubular body having a porous wall (page 15, line 1) defined by a plurality of interlaced circumferential lines (item 6, Fig. 1) forming a pathway motif or pattern (Fig. 2) wherein at least one line is closed onto itself (page 15, line 10);
- (c) each of the lines extends along an axis (item a-a, Fig. 2);
- (d) each of the lines comprises at least one plurality of modules (item 7, Fig. 2; page 15, line 17);
- (e) each module comprises three lobes, that is, two outer lobes (item 8, Fig. 2) and one inner lobe (item 9) disposed between the two outer lobes in the pathway of the pattern;
- (f) each lobe comprising one or more curved sections (item 10, Fig. 4bis) having concavities facing in the same direction, defining an apex (page 16, line 7) of the lobe;
- (g) the lobes opening alternately on opposite sides of the pathway of the pattern along the extent of the line (page 16, lines 11 - 13);

- (h) both of the outer lobes of the three lobes being extended by straight outer arms (page 16, line 17);
- (i) the at least one plurality of modules being arranged consecutively (page 16, line 20) so as to have successive outer arms (item 15, Fig. 2) which extend from the outer lobes in substantially opposite directions relative to the pathway of the pattern for two successive modules (page 16, line 23); and wherein,
- (j) for each module, the distance (d1, Fig. 2) between the apex of one of the outer lobes and the apex of the inner lobe of the same module is less than the distance (D2 or D3) between the apex of the same outer lobe and the apex of any outer lobe of an adjoining module;
- (k) for each line, there is at least one adjacent line which has a motif that is a mirror image (page 22, line 14) of the said line with respect to an axis parallel to the axis of the line;
- (l) at least one connecting element or bridge (24, Fig. 12) is provided between two adjacent lines; and
- (m) each said bridge directly connects two opposed outer lobes of two adjacent lines (Fig. 12), and each said bridge extends along a longitudinal axis parallel to the longitudinal axis of the tubular body;
- (n) one bridge is provided per module (page 24, lines 21 - 24), said bridge extending towards an adjacent line on the opposite side to the outer arms of the module; and
- (o) each said bridge is provided between two adjacent lines, for every five (page 25, line 17) complete lobes of a line, three outer lobes and two inner lobes.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The issues are:

- (1) whether claims 1 - 17, 19 - 21, 34, 40, 41, 43 - 46 and 51 - 53 would have been obvious from Dang in view of Fischell et al.,

- (2) whether claims 18, 22, 32,33, 25 - 39, 47 - 49 would have been obvious from those two references further in view of Callol et al.,
- (3) whether claim 42 would have been obvious from Dang in view of Fischell et al., and further in view of Moore, and
- (4) whether claims 55 and 56 would have been obvious from Dang in view of Fischell et al., and further in view of Ragheb et al.

ARGUMENT

(1) whether claims 1 - 17, 19 -21, 34, 40, 41, 43 - 46 and 51 - 53 would have been obvious from Dang in view of Fischell et al.

The examiner, when finally rejecting claim 1, explained at length what Dang discloses, and also identified what Dang does not disclose. He then found a teaching in Fischell which he deemed to supply the missing structure and he concluded this rendered claim 1 obvious. With respect, we submit that that conclusion resulted from the use of hindsight, i.e., combining features from different prior art documents in order to arrive to a result that one would reach only by reading the disclosure of the present application. Hindsight reasoning avoids the real issue of whether the newly claimed invention would have been obvious.

Dang discloses the limitations identified by letters a,b,c,d,f,h,k,l above. It does not disclose the limitations at e,g,i,j,m,n,o.

To reach the invention of claim 1, a person would have to make several changes to Dang not taught by Fischell.

Fischell does not solve any problem which Dang did not and neither reference suggests the possibility of the modifications the examiner posited. Neither those references themselves, nor sound reasoning, would have led a person of ordinary skill to the invention described in claim 1, at the time the invention was made and before

the teachings of this application were available. In particular, Fischell would not have induced one to so modify Dang as to include limitations at e, g, i, j, m, n and o, that is:

- (e) each module comprises three lobes, that is, two outer lobes (item 8, Fig. 2) and one inner lobe (item 9) disposed between the two outer lobes in the pathway of the pattern;
- (g) the lobes opening alternately on opposite sides of the pathway of the pattern along the extent of the line (page 16, lines 11 - 13);
- (i) the at least one plurality of modules being arranged consecutively (page 16, line 20) so as to have successive outer arms (item 15, Fig. 2) which extend from the outer lobes in substantially opposite directions relative to the pathway of the pattern for two successive modules (page 16, line 23); and wherein,
- (j) for each module, the distance (d1, Fig. 2) between the apex of one of the outer lobes and the apex of the inner lobe of the same module is less than the distance (D2 or D3) between the apex of the same outer lobe and the apex of any outer lobe of an adjoining module;
- (m) each said bridge directly connects two opposed outer lobes of two adjacent lines (Fig. 12), and each said bridge extends along a longitudinal axis parallel to the longitudinal axis of the tubular body;
- (n) one bridge is provided per module (page 24, lines 21 - 24), said bridge extending towards an adjacent line on the opposite side to the outer arms of the module; and
- (o) each said bridge is provided between two adjacent lines, for every five (page 25, line 17) complete lobes of a line, three outer lobes and two inner lobes.

We respectfully submit that, although some of the elements of the invention of claim 1 are found in the Dang and Fischell references, one would make the many modifications to those disclosures needed to arrive at the invention narrowly defined by claim 1 only if one used hindsight analysis. It is of course difficult to resist doing so, but the issue is whether a person of ordinary skill in the field of the invention

would have reached the invention of claim 1 merely by following the teachings of the references and using ordinary design skill. We submit that so many modifications would have been possible that, except with the detailed guidance provided by the present specification, arriving at the invention described with specificity in claim 1 would have been very unlikely – even if one knew of Dang and Fischell – and that certainly would have required more than routine experimentation.

(2) whether claims 18, 22, 32,33, 25 - 39, 47 - 49 would have been obvious from those two references further in view of Callol et al.,

These claims are deemed patentable for the limitations they inherit from claim 1. Callol (which was not applied against claim 1) does not overcome the shortcomings of Dang and Fischell et al. identified above.

(3) whether claim 42 would have been obvious from Dang in view of Fischell et al., and further in view of Moore

Claims 42 is deemed patentable for the limitations it inherits from claim 1. Moore is pertinent to the limitations added by this dependent claim, but does not overcome the deficiencies of the Dang and Fischell et al. references identified above, with respect to claim 1.

(4) whether claims 55 and 56 would have been obvious from Dang in view of Fischell et al., and further in view of Ragheb et al.

Claims 55 and 56 are deemed patentable for the limitations they inherit from claim 1. Ragheb is pertinent to the limitations added by these dependent claims, but does not overcome the deficiencies of the Dang and Fischell et al. references identified above, with respect to claim 1.

Respectfully submitted,

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CLAIMS APPENDIX

1. An expandable endolumenal prosthesis comprising, in the non-expanded configuration,

a tubular body extending along a longitudinal axis and having a distal end and a proximal end;

the tubular body having a porous wall defined by a plurality of interlaced circumferential lines forming a pathway motif or pattern wherein at least one line is closed onto itself;

each of the lines extends along an axis;

each of the lines comprises at least one plurality of modules;

each module comprises three lobes, that is, two outer lobes and one inner lobe disposed between the two outer lobes in the pathway of the pattern;

each lobe comprising one or more curved sections having concavities facing in the same direction, defining an apex of the lobe;

the lobes opening alternately on opposite sides of the pathway of the pattern along the extent of the line;

both of the outer lobes of the three lobes being extended by straight outer arms;

the at least one plurality of modules being arranged consecutively so as to have successive outer arms which extend from the outer lobes in substantially opposite directions relative to the pathway of the pattern for two successive modules; and wherein,

for each module, the distance between the apex of one of the outer lobes and the apex of the inner lobe of the same module is less than the distance between the apex of the same outer lobe and the apex of any outer lobe of an adjoining module;

for each line, there is at least one adjacent line which has a motif that is a mirror image of the said line with respect to an axis parallel to the axis of the line;

at least one connecting element or bridge is provided between two adjacent lines; and

each said bridge directly connects two opposed outer lobes of two adjacent lines, and each said bridge extends along a longitudinal axis parallel to the longitudinal axis of the tubular body;

one bridge is provided per module, said bridge extending towards an adjacent line on the opposite side to the outer arms of the module; and

each said bridge is provided between two adjacent lines, for every five complete lobes of a line, three outer lobes and two inner lobes.

2. A prosthesis according to Claim 1 in which the inner lobe of at least one module is extended by at least one straight inner arm.
3. A prosthesis according to Claim 2 in which both of the ends of the inner lobe are extended by straight arms.
4. A prosthesis according to Claim 1, in which at least one of the outer arms extends along an axis which is inclined to the longitudinal axis of the tubular body and is also inclined to the axis of the line to which the module belongs.
5. A prosthesis according to Claim 1, in which both of the outer arms of the module extend along respective axes which are inclined to the longitudinal axis of the tubular body and are also inclined to the axis of the line to which the module belongs.
6. A prosthesis according to Claim 1 in which the outer arms of the module extend away from the lobes along converging axes.
7. A prosthesis according to Claim 5 in which the arms have inclinations substantially close to the direction of the longitudinal axis of the prosthesis when the prosthesis is in the non-expanded configuration.

8. A prosthesis according to Claim 5 in which the inclination of the arms is selected in a manner such that, when the prosthesis is in the expanded configuration, the arms are arranged substantially close to the direction transverse the longitudinal axis of the prosthesis.
9. A prosthesis according to Claim 1 in which at least one outer arm of a module is shared with the adjacent module.
10. A prosthesis according to Claim 1 in which all of the outer arms of each module are shared with adjacent modules.
11. A prosthesis according to Claim 1 in which the outer arms are of equal extent.
12. A prosthesis according to Claim 1 in which the inner lobe is extended by two straight inner arms.
13. A prosthesis according to Claim 12 in which the inner arms are of equal extent.
14. A prosthesis according to Claim 1 in which the inner lobe is joined to the outer lobes by means of at least one inner arm.
15. A prosthesis according to Claim 1 in which the inner lobe and the inner arm or arms have an overall extent less than the overall extent of the outer lobes and the respective outer arms.
16. A prosthesis according to Claim 1 in which the outer and inner lobes with their outer arms and inner arms, respectively, have a non-uniform extent in a direction transverse the axis of the line.

17. A prosthesis according to Claim 1 in which the outer or inner arms have an extent which varies in the modules of the same line.
18. A prosthesis according to Claim 1 in which the outer or inner arms have an extent which varies in the modules disposed along the longitudinal axis of the tubular body of the prosthesis.
19. A prosthesis according to Claim 1 in which the outer arms of the same module have different extents.
20. A prosthesis according to Claim 1 in which at least one module has two inner arms of equal extent.
21. A prosthesis according to Claim 1 in which at least one module has two inner arms of different extents.
22. A prosthesis according to Claim 1 in which at least one module has a single inner arm.
23. A prosthesis according to Claim 1 in which at least one module comprises at least one lobe comprising at least one curved section of predefined extent suitable for determining the aperture of the cell which faces it.
24. A prosthesis according to Claim 1 in which at least one module comprises at least one lobe comprising at least one curved section of predefined extent suitable for arranging the arms substantially parallel to the longitudinal axis of the prosthesis when it is in the non-expanded or clenched configuration.
25. A prosthesis according to Claim 1 in which at least one module comprises at least one lobe comprising at least one curved section of predefined extent suitable for

arranging the arms substantially transverse the longitudinal axis of the prosthesis when it is in the expanded configuration.

26. A prosthesis according to Claim 1 in which at least one module comprises at least one lobe comprising a plurality of curved sections with concavities having the same orientation.

27. A prosthesis according to Claim 1 in which at least one module comprises at least one lobe comprising a plurality of curved sections with concavities having the same orientation and at least one interposed straight section.

28. A prosthesis according to Claim 1 in which the inner lobe is joined directly to one of the outer lobes.

29. A prosthesis according to Claim 1 in which all of the modules of a line have identical characteristics.

30. A prosthesis according to Claim 1 in which, in at least one line, two pluralities of modules are provided, alternating with one another so as to provide a series of a module of a first plurality and a module of the second plurality.

31. A prosthesis according to Claim 1 in which, in at least one line, the same module is repeated along the pathway of the line in a mirror-image arrangement with respect to an axis parallel to the axis of the line.

32. A prosthesis according to Claim 1 in which the prosthesis comprises lines comprising several pluralities of modules.

33. A prosthesis according to Claim 1 in which the prosthesis comprises three pluralities of modules.
34. A prosthesis according to Claim 1 in which at least one module has outer lobes that are disposed at different distances from the axis of the line.
35. A prosthesis according to Claim 1 in which, in at least one line, the pathway is interrupted so as to form an opening in the pattern suitable for the passage of an SDS guide wire.
36. A prosthesis according to Claim 35 in which the pathway is interrupted to an extent equal to one module.
37. A prosthesis according to Claim 35 in which the pathway is interrupted to an extent equal to five lobes.
38. A prosthesis according to Claim 35 in which the pathway is interrupted between two connecting bridges between the line and adjoining lines.
39. A prosthesis according to Claim 35 in which the pathway is interrupted in two adjacent lines.
40. A prosthesis according to Claim 1 in which at least one module is substantially M-shaped and is arranged so as to have outer arms directed substantially either towards the distal end or towards the proximal end.
41. A prosthesis according to Claim 1 in which the axis of the line is substantially perpendicular to the longitudinal axis of the tubular body.

42. A prosthesis according to Claim 41 in which the line axis is inclined to the longitudinal axis at an angle of between 5 degrees and 45 degrees and preferably between 10 and 30 degrees.
43. A prosthesis according to Claim 1 in which the line axis is straight or circumferential.
44. A prosthesis according to Claim 1 in which, for each line, there is at least one adjacent line which has a motif that is a mirror image of the said line with respect to an axis parallel to the axis of the line.
45. A prosthesis according to Claim 1 in which at least one connecting element or bridge is provided between two adjacent lines.
46. A prosthesis according to Claim 45 in which the bridge defines the interlacing of the lines.
47. A prosthesis according to Claim 45 in which the bridge comprises a bridge lobe.
48. A prosthesis according to Claim 45 in which the bridge comprises two bridge lobes.
49. A prosthesis according to Claim 45 in which the bridge comprises three bridge lobes.
50. (canceled)

51. A prosthesis according to Claim 45 in which, along the line, a bridge is provided between two adjacent lines, for every first or second outer lobe having the same orientation.
52. A prosthesis according to Claim 45 in which a bridge is provided for every module of the line.
53. A prosthesis according to Claim 1 in which, between two adjacent lines, a continuous closed pathway is provided, disposed between two bridges defining a cell.
54. A prosthesis according to Claim 53 in which a variation of the cell perimeter is provided along the longitudinal axis of the prosthesis.
55. A prosthesis according to Claim 1 in which the prosthesis comprises an external or internal coating.
56. A prosthesis according to Claim 55 in which the coating comprises a drug.
57. (canceled)

EVIDENCE APPENDIX

(Not applicable.)

RELATED PROCEEDINGS APPENDIX

(Not applicable.)